REMARKS

Summary of the Invention

The invention features a biologically pure culture of a newly identified single-celled organism, designated Spiky Rotating Cells (SPR). The invention also features methods for diagnosing an SPR infection, an instrument for collecting a secretion containing SPR and for detecting an SPR infection in the secretion, and methods for treating an SPR infection.

Summary of the Office Action

Claims 1, 5-7, 9, 10, 12, 14-17, 19-21, and 35-37 are pending. Claim 35 is considered allowable. Claim 16 would be allowable if rewritten in independent form. Claims 1 and 19-21 are rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. Claims 1, 5-7, 9-12, 16, 17, 19-21, and 36-37 are rejected under 35 U.S.C. § 112, second paragraph, for lack of clarity. Claims 1, 5, 7, 10, 12, and 19-21 are rejected under 35 U.S.C. § 102(b) for anticipation by Abou El Seoud et al. (J. Egypt. Soc. Parasitol. 28:263-270, 1998; hereinafter "Abou El Seoud"). Claims 1, 19-21 are rejected under 35 U.S.C. § 102(b) for anticipation by Monteiro-Leal et al. (Cell Motility and the Cytoskeleton 34:206-214, 1996; hereinafter "Monteiro-Leal"). Claims 5 and 10 are rejected under 35 U.S.C. § 102(b) for anticipation by Andrews et al. (U.S. Patent No. 5,300,491; hereinafter "Andrews"). Claim 17 is rejected under 35 U.S.C. § 102(b) for anticipation by Birthistle et al. (Genitourin Med. 72:445-452, 1996; hereinafter "Birthistle") and Larson (U.S. Patent No. 6,180,136; hereinafter "Larson"). Claims 5, 7, 9, 10, 19-21, and 36-37 are rejected under 35 U.S.C. § 102(a) for anticipation by van der Schee et al. (J. Clin. Micro. 37:4127-4130, 1999; hereinafter "van der Schee"). Claims 5 and 6 are rejected under 35 U.S.C. § 102(e) for anticipation by Kritzman et al. (U.S. Patent No. 5,660,790; hereinafter "Kritzman").

Claim 14 is rejected under 35 U.S.C. § 102(b) for anticipation by Bush et al. (Amer. J. Roentgenology 144:795-799, 1985; hereinafter "Bush"). Finally, claim 15 is rejected under 35 U.S.C. § 102(b) for anticipation by Nucci (U.S. Patent No. 5,063,930; hereinafter "Nucci") and Hardy (U.S. Patent No. 2,644,879; hereinafter "Hardy"). By this reply, Applicant cancels claim 16, amends claims 1, 5, 14, 15, and 17, and addresses each of the Examiner's rejections below.

Support for the Amendments

Support for the amendments to claims 1, 5, and 17 is found in the specification on page 7, lines 12-21, page 10, lines 8-15, and Figures 3 and 4. Although the term "circumferential" is not present in the specification with respect to spiky projections of the cell membrane, as is presently recited in claims 1, 5, and 17, *ipsis verbis* disclosure is not necessary to satisfy the written description requirement of 35 U.S.C. § 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question. Here, Figure 3 of the specification clearly shows that the SPR organism has spiky membrane projections that surround its circumference. Based on the evidence provided in Figure 3, one skilled in the art would reasonably conclude that the spiky membrane projections of the SPR organism are circumferential, and therefore, recitation of this term is not new matter (*In re Edwards*, 568 F.2d 1349, 1351-52, 196 U.S.P.Q. (BNA) 465, 467 (CCPA 1978).

Similarly, the term "behavior", present in amended claims 1, 5, and 17, is also not new matter. The specification clearly discloses that the SPR organism switches between a solitary living stage and a clustering stage "in which many organisms come together to form large colonies" (see, e.g., page 10, lines 8-15, of the specification). The skilled artisan would appreciate that the switch from a solitary living stage to a colonial clustering stage is a behavior

of the SPR organism that is modified according to, e.g., its living environment, access to nutrients, and reproductive needs. Therefore, recitation of this term is not new matter.

Support for the amendment to claims 14 and 15 is found in Fig. 1 and on page 9, lines 8-17, of the specification. Further support for the amendment to claim 14 is found in cancelled claim 16. No new matter is added by this amendment.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1 and 19-21 are rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The rejected claims are directed to a biologically pure culture of a single-celled organism, termed "SPR" for spiky rotating cells, which Applicant has identified as being the causative agent in nongonococcal urethritis. The Examiner states:

> The claims are directed to a genus of single-cell organisms spiky rotating cells that have seven recited biological characteristics, but only a single species of SPR cell has been described. A single species does not describe the claimed highly variable genus of cells that may have any number of spiky membrane projections, and is a provisional protozoan. How additional species of the claimed genus would be similar or different from the single disclosed species of SPR has not been described. What has not been described, has not been enabled. (Office Action, pp. 6-7.)

Thus, the Examiner asserts that the instant specification fails to provide an adequate written description of the present invention within the full scope of the claims. Applicant respectfully traverses this rejection.

In order to fulfill the written description requirement of § 112, the patent specification does not need to describe exactly all the subject matter that is claimed. *In re Daniels*, 114 F.3d 1452, 46 U.S.P.Q.2d 1788 (Fed. Cir. 1998); *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 227 U.S.P.Q. 117 (Fed. Cir. 1985). Rather, the specification must clearly allow a person of

ordinary skill in the art to recognize that the inventor has invented what is claimed. *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 U.S.P.Q.2d 1498 (Fed. Cir. 1998). In applying this standard, the Federal Circuit has held that the specification must convey with reasonable clarity to a skilled artisan that the inventor "was in possession of the invention" at the time of filing. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991).

Claim 1 has been amended to clarify the biological characteristics that distinguish the single-celled organism, SPR, over other prior art organisms, and now recites that the organism has "multiple circumferential spiky membrane projections of the cell membrane" and exhibits "periodic clustering behavior to form colonies." As is discussed below, these characteristics, in combination with the five other recited characteristics, are not associated with any other art-described organism and serve to clearly distinguish the presently claimed organism from these other organisms. Therefore, the skilled artisan can clearly distinguish an SPR organism from another organism, e.g., *Trichomonas vaginalis* or *Tritrichomonas foetus*, by using these characteristics.

The definition put forth in claims 1, 5, and 17 defines the essential characteristics of an SPR organism. The definition is based on the unique structural and behavioral features of this organism. These features distinguish an SPR organism from all other known protozoal organisms. The features recited in claims 1, 5, and 17 are necessary and sufficient for the identification of an SPR organism. They define the necessary conditions for identifying an SPR organism in that all of these characteristics must be present for an organism to be recognized as belonging to the taxon SPR. If an organism lacks any one of these characteristics, it is not an SPR organism.

Furthermore, this definition puts forth the sufficient conditions for the identification of an organism as belonging to the taxon SPR. Even though an organism may have additional features, as long as it exhibits the seven defining characteristics recited in claims 1, 5, and 17, it is an SPR organism. Therefore, additional species of the claimed genus are similar in so far as they have all of the seven defining characteristics of claims 1, 5, and 17.

The M.P.E.P. § 2163(II)(A)(3)(a)(ii) states that the written description requirement can be satisfied through sufficient disclosure of relevant, identifying characteristics of a claimed genus, which Applicant's specification clearly provides. Moreover, in *Regents of the University of California v. Eli Lilly & Co.,* the Federal Circuit acknowledged that "every species in a genus need not be described in order that a genus meets the written description requirement." 43 U.S.P.Q.2d at 1405 (citing *Utter v. Hiraga*, 845 F.2d 993, 6 U.S.P.Q2d 1709 (Fed. Cir. 1988) ("A specification may, within the meaning of § 112, ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.") Furthermore, "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces" (M.P.E.P. § 2163(II)(A)(3)(a)(ii)). Thus, the Examiner's argument that the SPR organism is the only species described in the specification is not sufficient to establish that the specification lacks an adequate written description for the claimed invention. To the contrary, it is not necessary for the specification to describe other species of SPR in order to satisfy the written description requirement since, as discussed above, the relevant identifying characteristics and biological properties of the organism has been provided. For this reason, Applicant respectfully submits that the instant specification provides an adequate written description of the claimed invention. The § 112 rejection should, therefore, be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 5-7, 9-12, 16, 17, 19-21, and 36-37 are rejected under 35 U.S.C. § 112, second paragraph, for lack of clarity. The Examiner states that the phrase "periodic colonial clustering" recited in claims 1, 5-7, 9-10, 12, 17, 19-21, and 36-37, "is not an art recognized phrase to describe a specific phenotypic or genotypic biological or chemical characteristic of bacterial or protozoan growth...The phrase 'periodic colonial clustering' does not distinctly claim Applicant's invention." (Office Action, p. 7).

Claims 1, 5, and 17 have been amended to recite "periodic clustering behavior to form colonies," which reflects that the periodic clustering to form colonies occurs as a deliberate action of the SPR organism and is not simply an artifact of laboratory manipulation as occurs due to streaking of an organism, such as a bacterium, on an agar plate. The term "periodic clustering behavior" does not define the result of a "standardized" protocol (e.g., a growth pattern that results from streaking an organism on a growth medium-containing petri dish), but rather, a characteristic behavior (i.e., clustering) of the SPR organism that occurs over time (i.e., periodically). The present amendment to claims 1, 5, and 17 clarifies this issue, and therefore, the rejection of claims 1, 5-7, 9-10, 12, 17, 19-21, and 36-37 under 35 U.S.C. § 112, second paragraph, for lack of clarity should be withdrawn.

The Examiner also states that claim 16 depends from itself and therefore is unclear. Applicant has cancelled claim 16. Therefore, this rejection should now be withdrawn as well.

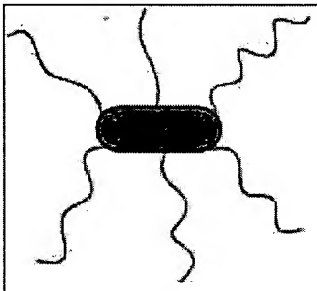
Rejections Under 35 U.S.C. § 102(b)

Abou El Seoud

Claims 1, 5, 7, 10, 12, and 19-21 are rejected under 35 U.S.C. § 102(b) for anticipation by Abou El Seoud. The Examiner states that although the phrase "periodic colonial clustering" has been used to define a functional characteristic and patentable novelty of the claimed composition, "this phrase is not an art recognized phrase to describe bacterial or protozoan growth" (Office Action, p. 4). Furthermore, isolates of the protozoan of Abou El Seoud would periodically produce colonies when prepared using the art-known technique of streaking an organism onto a selective growth-medium-containing petri dish. Therefore, "Applicant's arguments have not distinguished the claimed invention from the applied prior art" (Office Action, p. 4). Applicant respectfully disagrees, but has amended claim 1 to recite "periodic clustering behavior to form colonies," which clarifies that the periodic colonial clustering exhibited by the SPR organism is behavior-driven and not simply due to experimental manipulation.

As is discussed above, the specification clearly teaches that the SPR organism periodically undergoes a switch from a solitary single-celled organism to a communal clustering organism. When this behavioral change occurs, the SPR organism actually moves itself toward other SPR organisms to form clusters of several cells. In contrast, *Trichomonas vaginalis,* which is described by Abou El Seoud, is not know to form clusters of cells due to a *behavior* of the organism, nor is this an inherent behavioral property of *T. vaginalis*. Although *T. vaginalis* may form clusters of cells when applied to a petri dish and cultured, this is merely an artifact of the biological technique; the cell clusters would not result from a behavioral shift of the organism from a solitary stage to a communal stage, as occurs with the SPR organism of present claim 1. For this reason, the organism of present claim 1 is not taught or suggested by Abou El Seoud.

In addition, *T. vaginalis* is a flagellated protozoan. Flagella are rigid structures made up of microtubules that rotate like a propeller. They are designed to move the cell itself or to move substances over or around the cell. The diameter of a flagellum is ~20 nm wide and a length 10 times the diameter of cell (about 100 nm). The figure below demonstrates some of the more common flagellar arrangements.

Polar or Monotrichous	Lophotrichous	Peritrichous
		

In contrast to *T. vaginalis*, the organism of present claim 1 does not possess flagella, but rather "multiple *circumferential* spiky membrane projections of the cell membrane," as is now recited in present claim 1. These deformations are not present in *T. vaginalis*. For this reason as well, the organism of present claim 1 is not taught or suggested by Abou El Seoud. Because Abou El Seoud fails to teach or suggest an organism that satisfies all of the limitations of present claim 1, and claims dependent therefrom, or a method of diagnosing an organism, as is recited in claim 5, and claims dependent therefrom, Applicant respectfully requests that the rejection of claims 1, 5, 7, 10, 12, and 19-21 under 35 U.S.C. § 102(b) over Abou El Seoud be withdrawn.

Monteiro-Leal

The Examiner also rejects claims 1 and 19-21 under 35 U.S.C. § 102(b) for anticipation by Monteiro-Leal. The Examiner states that "Monteiro-Leal et al. disclose a biologically pure

culture of a single celled organism (see Figure 1, page 207), that was cultured to produce a large colony of the protozoan" (Office Action, p. 5). Applicant respectfully disagrees.

Applicant first points out that Monteiro-Leal describes *Tritrichomonas foetus*, which is a pathogen of cattle, not humans (see, e.g., p. 206 of Monteiro-Leal). Therefore, *T. foetus* is not an "organism that causes disease in humans", as is recited in present claim 1, and claims dependent therefrom. Second, as is discussed above, claim 1 has been amended to recite that the SPR organism exhibits "periodic clustering behavior to form colonies" and "multiple circumferential spiky membrane projections." *Tritrichomonas foetus*, which is described by Monteiro-Leal, does not exhibit either of these biological characteristics. As is clearly described by Monteiro-Leal, *T. foetus* have three anterior flagella and one undulating membrane formed by the association of the recurrent flagellum and part of the cell surface (Figure 1, Monteiro-Leal). The SPR organism of present claim 1, and claims dependent therefrom, does not possess a flagellum, but rather, multiple circumferential spiky membrane projections. Figure 1 of Monteiro-Leal clearly indicates that *T. foetus* does not exhibit multiple circumferential spiky membrane projections. Furthermore, contrary to the Examiner's assertion, Monteiro-Leal fails to teach or suggest that *T. foetus* exhibits any clustering behavior, much less periodic clustering behavior, as is presently recited in claim 1. Monteiro-Leal merely states that "[t]he K strain of *T. foetus* was cultivated in TYM medium for 36 h at 37°C" (p. 207 of Monteiro-Leal). This passage, while indicating that *T. foetus* likely multiplied (i.e., "was cultivated"), fails to indicate that individual cells of *T. foetus* came together to form a cluster or that this characteristic was observed or used by Monteiro-Leal as a distinguishing biological characteristic for identification or diagnosis of the organism. For these reasons, Monteiro-Leal fails to teach or suggest an organism that satisfies all of the limitations of present claim 1, and claims dependent therefrom, or a method of diagnosing

an organism, as is recited in claim 5, and claims dependent therefrom. Therefore, Applicant respectfully requests that the rejection of claims 1 and 19-21 under 35 U.S.C. § 102(b) over Monteiro-Leal be withdrawn.

Andrews

The Examiner also rejects claims 5 and 10 under 35 U.S.C. § 102(b) for anticipation by Andrews. The Examiner states:

> Andrews does carry out the method steps of obtaining a sample from a patient, wherein the sample...is a human sample...[and] testing for the presence of a single celled organism that is spiky and rotating (motile protozoan)...The SPR infection causing pathogen diagnosed by Andrews et al, is a protozoan, the protozoan evidencing the recited characteristics. (Office Action, p. 5.)

Applicant respectfully disagrees.

The M.P.E.P. § 2131 states that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." As was discussed in the previous Reply to Office Action, filed with the Request for Continued Examination on April 4, 2004, Andrews fails to disclose a method for diagnosing an organism that exhibits all of the biological and morphological characteristics recited in present claim 5 (e.g., disease in humans, periodic clustering behavior to form colonies, and multiple circumferential spiky projections of the cell membrane). Andrews merely describes a method of treating *Entamoeba histolytica*, *Trichomonas vaginalis*, *Giardia lamblia*, *Cryptosporidium parvum*, *Tritrichomonas foetus*, and *Tritrichomonas gallinae*; organisms which do not exhibit all of the limitations of present claim 5.

T. foetus and *T. gallinae* are animal pathogens that do not cause disease in humans. Therefore, these organisms do not meet the limitations of present claim 1. *G. lamblia* and *T. vaginalis* also do not meet the limitations of present claim 1 because they both possess flagellum rather than multiple circumferential spiky membrane projections (see above for discussion of *T. vaginalis*). Furthermore, neither *G. lamblia* or *T. vaginalis* exhibit periodic clustering behavior to form colonies, as is now required by claim 5. Finally, *C. parvum* also does not exhibit all of the biological characteristics recited in present claim 5, because it lacks "a spherical shape measuring approximately 7-8 μm in diameter." On the contrary, *C. parvum* is a small parasite measuring 3-5 μm in diameter. Further, *C. parvum* does not exhibit either periodic clustering behavior to form colonies or circumferential spiky membrane projections.

Because none of the organisms described by Andrews exhibits all of the characteristics of the organism recited in present claim 5, the method of Andrews would fail to enable one skilled in the art to diagnose an SPR infection. For this reason, the rejection of claims 5 and 10 under 35 U.S.C. § 102(b) over Andrews should be withdrawn.

Birthistle

Claim 17 is rejected under 35 U.S.C. § 102(b) for anticipation by Birthistle. The Examiner states:

> ...Birthistle and Larson both diagnose a disease in a patient that [sic] are caused by a SPR (Monteiro-Leal and El-Seoud provide evidence of protozoan species that meet the functional limitations recited in the claims, and the organisms treated by [sic] Bisthistle and Larson are protozoan organisms), wherein the patient may be a mammal, specifically a human. (Office Action, p. 6.)

Applicant respectfully disagrees.

Birthistle discloses treating a patient diagnosed with urethritis associated with microsporidia. Microsporidia is an intracellular protozoan parasite. Claim 17 is directed to a method of treating an SPR infection by first diagnosing an SPR infection, which is performed by, *inter alia*, detecting an extracellular organism. The SPR organism is also identified by multiple circumferential spiky membrane projections and its periodic clustering behavior to form colonies, as is now recited in claim 17. Microsporidia exhibit none of these characteristics. Because Birthistle fails to teach or suggest a method that includes diagnosing an SPR infection based on the identification of an organism that exhibits all of the recited biological characteristics of claim 17, Birthistle fails to teach or suggest all of the limitations of claim 17, as is required (see M.P.E.P. § 2131, *supra*). Therefore, Applicant respectfully requests that the rejection of claim 17 under 35 U.S.C. § 102(b) over Birthistle be withdrawn.

Larson

Claim 17 is rejected under 35 U.S.C. § 102(b) for anticipation by Larson. The Examiner states that Larson discloses diagnosing a disease in a patient that is caused by an SPR organism. Applicant respectfully disagrees.

The Examiner points to col. 6, lines 32-37, of Larson for evidence that Larson discloses treating a mammal. This passage of Larson merely states that "[i]n preferred embodiments, the suspensions of the present invention may be made into an injectable syringeable form and administered to the mammal by parenteral administration. The mammal may be a bovine, an equine, a porcine, a canine, a feline, or any mammal" (col. 6, lines 32-37). In previous Office Actions, the Examiner has pointed to claims 33-41 of Larson for evidence of the diagnostic and treatment steps of claim 17. Claims 33-41 of Larson merely discloses a method for treating an

infection caused by, e.g., a protozoan, by administering microcrystals containing an antibiotic encapsulated by a phospholipid layer (see, e.g., claims 33 and 41 of Larson). Larson clearly fails to teach or suggest a diagnostic step which requires detecting an organism that exhibits all of the biological characteristics recited in claim 17. For this reason, Larson fails to teach or suggest all of the limitations of claim 17, as is required (see M.P.E.P. § 2131, *supra*). Therefore, Applicant respectfully requests that the rejection of claim 17 under 35 U.S.C. § 102(b) over Larson be withdrawn.

Van der Schee

Claims 5, 7, 9, 10, 19, 20-21, and 36-37 are rejected under 35 U.S.C. § 102(b) for anticipation by Van der Schee. The Examiner argues that Van der Schee discloses all of the elements of present claims 5, 7, 9, 10, 19, 20-21, and 36-37. Applicant respectfully disagrees.

Applicant notes that although claim 19 was included in the rejected claims recited in the Office Action, it is dependent on claim 1, which is not rejected over Van der Schee. Therefore, Applicant believes that the inclusion of claim 19 in the rejection is an error and has not addressed its patentability with respect to this reference.

Van der Schee discloses an improved method for diagnosing *T. vaginalis* using PCR. Van der Schee fails to disclose any additional diagnostic steps that include identifying an organism that exhibits multiple circumferential spiky projections of the cell membrane and periodic clustering behavior. As is discussed above, *T. vaginalis* does not exhibit these characteristics and is distinct from the SPR organism based on the biological characteristics recited in present claim 5 (see discussion of Abou El Seoud above). Therefore, the method of Van der Schee, which fails to employ all of the steps of present claim 5, and claims dependent

therefrom, would fail to identify an SPR organism and, consequently, diagnose an SPR infection. For this reason, Van der Schee fails to teach or suggest all of the limitations of claims 5, 7, 9, 10, 20-21, and 36-37, as is required (see M.P.E.P. § 2131, *supra*). Therefore, Applicant respectfully requests that this rejection be withdrawn.

Kritzman

Claims 5 and 6 are rejected under 35 U.S.C. § 102(b) for anticipation by Kritzman. The Examiner states that Kritzman discloses obtaining a sample from a patient and testing the pH of the sample for the presence of *T. vaginalis*, and that this disclosure anticipates the claimed invention. Applicant respectfully disagrees.

Kritzman describes a method for determining the presence of a pathological state in a person, e.g., bacterial vaginosis, by automatically analyzing bodily secretions, e.g., vaginal secretions, collected in a device (i.e., an absorbent pad) worn by the person (see, e.g., col. 3, lines 56-67 and col. 8, lines 53-67). Diagnosis of a pathological condition using the Kritzman device occurs by observing a change in the color of the absorbent pad of the device due to an increase in the pH of a bodily secretion of the user. The absorbent pad is further analyzed biochemically using, e.g., PCR, LCR, RT-PCR, immunoassay, ELISA, RIA, FACS, gel electrophoresis, microscopy, immuno-fluorescence, SNIRPS analysis, and/or restriction fragment length polymorphism (RFLP) analysis to confirm the diagnosis (see col. 9, lines 23-40). None of these detection methods, with the exception of microscopy, allows testing a sample for the presence of an organism by detecting an organism with all of the biological characteristics recited in present claim 5. Although microscopy could be used to detect infection of a person by an SPR organism, Kritzman fails to teach or suggest how one would use microscopy to detect an SPR organism.

For this reason, Kritzman fails to teach or suggest all of the limitations of present claims 5 and 6. Accordingly, Applicant respectfully requests that the rejection of claims 5 and 6 under 35 U.S.C. § 102(b) for anticipation by Kritzman be withdrawn.

Bush

Claim 14 is rejected under 35 U.S.C. § 102(b) for anticipation by Bush. The Examiner states that "Bush et al disclose the instantly claimed invention directed to an instrument that comprises: a handle...and a means that comprises a loop region" (Office Action, p. 8). Applicant has amended claim 14 to recite that the device additionally comprises a pH sensor positioned adjacent the collecting means. Bush fails to teach or suggest a device that comprises a handle portion, a collecting means comprising a loop region, and a pH sensor. Because Bush fails to teach or suggest all of the elements of claim 14, as presently amended, Applicant respectfully requests that the rejection of claim 14 under 35 U.S.C. § 102(b) for anticipation by Bush be withdrawn.

Nucci

Claim 15 is rejected under 35 U.S.C. § 102(b) for anticipation by Nucci. The Examiner states that Nucci discloses an instrument that has both a handle portion, a means for collecting a secretion sample of a female patient, and a pH indicator, and therefore, Nucci anticipates the invention of claim 15. Applicant respectfully disagrees.

Nucci discloses a disposable probe that is designed as "a small pipe with a closed head, a hole provided near the head and one or more pH indicators or other indicators disposed within the probe" (Abstract). The Nucci device functions by collecting vaginal liquid that enters

through the oval hole of the device and flows from the head to the opposite end upon introduction of the device into the vagina (see col. 2, lines 52-59). Contact of the vaginal secretion with the indicator allows determination of the pH of the sample.

In contrast to the Nucci device, which contains a collecting means (the oval hole) *near* the end of the head of the device, the collecting means (i.e., the loop region) of the device of present claim 15, as amended, is positioned at the *end* of the device opposite the handle portion (see also Figure 1 of Applicant's specification). Furthermore, the Nucci device cannot be used to collect a vaginal sample or detect its pH under conditions in which the vagina is dry because it requires that the vaginal liquid flows into the device so that it can come into contact with the indicator. The device of present claim 15, on the other hand, can be used to obtain a vaginal sample and detect the pH of that sample even under dry conditions because the device can be used to scrape the vaginal mucosa, if necessary, to obtain the sample and because the pH indicator is located so that it comes into direct contact with the vaginal mucosa upon insertion of the device into the vagina. The pH indicator of the Nucci device is positioned inside a pipe and never comes into direct contact with the vaginal mucosal. For all of the reasons provided above, Nucci fails to teach or suggest all of the elements of present claim 15. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Hardy

Claim 15 is rejected under 35 U.S.C. § 102(b) for anticipation by Hardy. The Examiner states that Hardy anticipates claim 15 by disclosing an instrument for collecting a sample from a female patient, in which the instrument comprises a handle portion and a means for collecting the

secretion, which includes a loop region with an opening and one or more indicators for pH determination. Applicant respectfully disagrees.

Hardy describes an instrument for testing pH values of body canal liquids. The handle portion of Hardy's instrument includes a loop region with an opening positioned at the handle portion, presumably to allow the user to grasp the device by inserting a finger through the hole (see Figures 1 and 2, and col. 2, lines 1-4). In contrast, the loop region of the device of present claim 15 is the collecting means of the device and is separated from the handle portion of the device by being positioned at the end of the device opposite the handle portion. Therefore, rather than serving as a means to grasp the device, as is disclosed in Hardy, the loop region of the device of claim 15 is the collecting means of the device and is inserted into the vagina of a subject. Accordingly, the Hardy device is structurally distinct from the device of present claim 15. For this reason, Applicant respectfully requests that the rejection of claim 15 for anticipation over Hardy be withdrawn.

CONCLUSION

Applicant submits that the claims are now in condition for allowance, and such action is respectfully requested.

Enclosed is a petition to extend the period for replying for three months, to and including April 29, 2004, and a check for the fee required under 37 C.F.R. § 1.17(a).

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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